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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/010,907 | 11/02/2001 | David Schaible | 541.1029US2 | 6133 |
| 23280 | 7590 | 02/25/2004 | EXAMINER | |
| DAVIDSON, DAVIDSON & KAPPEL, LLC 485 SEVENTH AVENUE, 14TH FLOOR NEW YORK, NY 10018 | | | HALPERN, MARK | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1731 | |

DATE MAILED: 02/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------------------|--|--|
| Office Action Summary | Application No. 10/010,907 | Applicant(s) SCHAIBLE ET AL. | |
| | Examiner Mark Halpern | Art Unit 1731 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>11/19/03</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1) Acknowledgement is made of Response to Notice of Non-Compliant Amendment received 12/8/2003. Amendment received 11/7/2003, is under consideration.

Applicants amend claims 1, 12, 18.

Claim Objections

2) Claim 28 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claim 28 is a repeat of claim 27 and does not further limit the subject matter of claim 1.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3) Claims 1-3, 5-28, are rejected under 35 U.S.C. 103(a) as being unpatentable over Jollez (WO 99/60027) in view of Toshkov (3,954,727), and further in view of Gross (6,344,109).

Claims 1, 11-12: Jollez teaches of a process of making a high purity microcrystalline cellulose without the use of any mineral acids (Jollez, Abstract). Prior to placing the pulp into a reactor, the pulp is prepared by repulping in order to make it less condense, and the pulp is subjected to filtration and trituration. Jollez is silent on cooking of the pulp in a reactor (Jollez, pg. 3, lines 21-26, and pg. 7, line 30 to pg. 8, line 5). Toshkov discloses a process of preparing microcrystalline cellulose, wherein the pulp is cooked in a reactor by heating the reactor to a desired temperature and pressure for a duration of time to obtain a desired degree of polymerization. The process temperature, pressure and duration are disclosed. (Toshkov, col. 2, lines 28-68). It would have been obvious, to one skilled in the art at the time the invention was made, to combine the teachings of Jollez and Toshkov, because such a combination would provide a high quality hydrolysis product of Jollez obtained under stable and safe conditions of Toshkov. After cooking the Toshkov reactor is cooled with water. It would have been obvious that water-cooling of the reactor would necessitate a partial depressurizing of the reactor in order to keep structural integrity of the reactor. The microcrystalline cellulose is separated from the hydrolysate; it is filtered, de-aggregated in a colloid mill, bleached and dried (Toshkov, col. 2, lines 2-63). Jollez and Toshkov are silent on pressing and decompacting of the pulp in the pulp preparation stage. Gross discloses the process of making a cellulose product, wherein pulp is prepared by first blotting of the pulp to remove water from an aqueous solution and then fluffing of the pulp (Gross, col. 9, lines 22-40). This reads on the claimed pressing of the pulp and decompacting of the pulp. It would have been obvious, to one skilled in the art at

the time the invention was made, to combine the teachings of Jollez and Toshkov with Gross, because such a combination would provide for a starting pulp that is clean and readily reactive in the reactor of Jollez and Toshkov and thus result in a product of high quality and of a high absorbency as disclosed by Gross (col. 1, lines 33-38).

Claim 2: application of a shearing force is disclosed by Jollez in Abstract.

Claims 3, 6: deaggregating performed using a colloidal mill is disclosed by Toshkov (col. 1, lines 40-45).

Claim 5: the water is added to the microcrystalline cellulose and the solution alkalized to a pH above 5.5 (Toshkov, col. 2, lines 54-60).

Claims 7, 13: repulping is carried out at a consistency of 2 % (Jollez, pg. 12, line 19).

Claims 8, 14: cooking is carried out with the addition of diluted hydrochloric acid (Toshkov, col. 1, lines 21-25).

Claims 9-10, 15-16: cooking is carried out at temperature range of 200-240 °C for a time period varying from 4 to 24 minutes, depending on the desired degree of polymerization (Jollez, pg. 9, lines 4-7).

Claims 17-23: Jollez discloses cellulose bleaching with hydrogen peroxide at temperature of 60-120 °C, pressure from 60 to 120 psi, under air pressure of 60-120 psi, in the presence of magnesium sulfate (Jollez, pg. 9, lines 11-16).

Claims 24-26: pH is disclosed from 3.5-7.7 (Jollez, pg. 11, line 9).

Claims 27-28: it would have been obvious that the desired degree of polymerization is stable since it can be tailored and optimized (Jollez, pg. 7, lines

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18-26).

4) Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jollez in view of Toshkov, further in view Gross, and further in view of Hanna (6,228,213).

Jollez in view of Toshkov and Gross, is applied as above for claim 1, Jollez in view of Toshkov and Gross disclose the drying step, however the references fail to disclose that the drying is performed with a spray dryer. Hanna discloses a process of making pharmaceutical grade microcrystalline cellulose (Hanna, col. 1, lines 15-33) wherein the drying of the microcrystalline cellulose is performed using a spray dryer (Hanna, col. 4, 58-64). It would have been obvious, to one skilled in the art at the time the invention was made, to combine the teachings of Jollez, Toshkov, Gross and Hanna, because such a combination would lower drying time in the process of Jollez as disclosed by Hanna (Hanna, col. 4, lines 55-58).

Response to Amendment

5) Claim 18 objection is withdrawn in view of amended claim.

6) Claims 1-28, rejection under 35 U.S.C. 112, first paragraph, is withdrawn in view of amended claims.

7) Claims 1-28, rejection under 35 U.S.C. 112, second paragraph, is withdrawn in view of amended claims.

8) Claims 1-3, 5-28, rejection under 35 U.S.C. 103(a) as being unpatentable over Toshkov (3,954,727) in view of Jollez (WO 99/60027), and further in view of Nimz (5,074,960), is withdrawn in view of further search of art in prior art.

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9) Claim 4 rejection under 35 U.S.C. 103(a) as being unpatentable over Toshkov in view of Jollez, and Nimz, and further in view of Hanna (6,228,213), is withdrawn in view of further search of art in prior art.

Conclusion

10) Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Halpern whose telephone number is 571-272-1190. The examiner can normally be reached on Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Steven Griffin can be reached on 571-272-1189. The fax phone number for the organization where this application is assigned is 703-872-9309.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1700.



Mark Halpern
Patent Examiner
Art Unit 1731